

§ 410.38

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month in which the last screening colonoscopy was performed.

(f) *Condition for coverage of screening colonoscopies.* Medicare Part B pays for a screening colonoscopy if it is performed by a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

(g) *Limitations on coverage of screening colonoscopies.* (1) Effective for services furnished on or after July 1, 2001, except as described in paragraph (g)(3) of this section, payment may be made for a screening colonoscopy performed for an individual who is not at high risk for colorectal cancer as described in paragraph (a)(3) of this section, after at least 119 months have passed following the month in which the last screening colonoscopy was performed.

(2) Payment may be made for a screening colonoscopy performed for an individual who is at high risk for colorectal cancer as described in paragraph (a)(3) of this section, after at least 23 months have passed following the month in which the last screening colonoscopy was performed, or, as provided in paragraphs (h) and (i) of this section, the last screening barium enema was performed.

(3) In the case of an individual who is not at high risk for colorectal cancer as described in paragraph (a)(3) of this section but who has had a screening flexible sigmoidoscopy performed, payment may be made for a screening colonoscopy only after at least 47 months have passed following the month in which the last screening flexible sigmoidoscopy was performed.

(h) *Conditions for coverage of screening barium enemas.* Medicare Part B pays for a screening barium enema if it is ordered in writing by the beneficiary's attending physician.

(i) *Limitations on coverage of screening barium enemas.* (1) In the case of an individual age 50 or over who is not at high risk of colorectal cancer, payment may be made for a screening barium enema examination performed after at least 47 months have passed following the month in which the last screening barium enema or screening flexible sigmoidoscopy was performed.

(2) In the case of an individual who is at high risk for colorectal cancer, payment may be made for a screening bar-

ium enema examination performed after at least 23 months have passed following the month in which the last screening barium enema or the last screening colonoscopy was performed.

[62 FR 59100, Oct. 31, 1997, as amended at 66 FR 55329, Nov. 1, 2001; 67 FR 80040, Dec. 31, 2002; 77 FR 69362, Nov. 16, 2012]

§ 410.38 Durable medical equipment: Scope and conditions.

(a) Medicare Part B pays for the rental or purchase of durable medical equipment, including iron lungs, oxygen tents, hospital beds, and wheelchairs, if the equipment is used in the patient's home or in an institution that is used as a home.

(b) An institution that is used as a home may not be a hospital or a CAH or a SNF as defined in sections 1861(e)(1), 1861(mm)(1) and 1819(a)(1) of the Act, respectively.

(c) *Power mobility devices (PMDs)*—(1) *Definitions.* For the purposes of this paragraph, the following definitions apply:

Physician has the same meaning as in section 1861(r)(1) of the Act.

Power mobility device means a covered item of durable medical equipment that is in a class of wheelchairs that includes a power wheelchair (a four-wheeled motorized vehicle whose steering is operated by an electronic device or a joystick to control direction and turning) or a power-operated vehicle (a three or four-wheeled motorized scooter that is operated by a tiller) that a beneficiary uses in the home.

Prescription means a written order completed by the physician or treating practitioner who performed the face-to-face examination and that includes the beneficiary's name, the date of the face-to-face examination, the diagnoses and conditions that the PMD is expected to modify, a description of the item (for example, a narrative description of the specific type of PMD), the length of need, and the physician or treating practitioner's signature and the date the prescription was written.

Treating practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as those terms are defined in section 1861(aa)(5) of the Act, who has conducted a face-to-face examination of the beneficiary.

Supplier means an entity with a valid Medicare supplier number, including an entity that furnishes items through the mail.

(2) *Conditions of payment.* Medicare Part B pays for a power mobility device if the physician or treating practitioner, as defined in paragraph (c)(1) of this section meets the following conditions:

(i) Conducts a face-to-face examination of the beneficiary for the purpose of evaluating and treating the beneficiary for his or her medical condition and determining the medical necessity for the PMD as part of an appropriate overall treatment plan.

(ii) Writes a prescription, as defined in paragraph (c)(1) of this section that is provided to the beneficiary or supplier, and is received by the supplier within 45 days after the face-to-face examination.

(iii) Provides supporting documentation, including pertinent parts of the beneficiary's medical record (for example, history, physical examination, diagnostic tests, summary of findings, diagnoses, treatment plans and/or other information as may be appropriate) that supports the medical necessity for the power mobility device, which is received by the supplier within 45 days after the face-to-face examination.

(3) *Exceptions.* (i) Beneficiaries discharged from a hospital do not need to receive a separate face-to-face examination as long as the physician or treating practitioner who performed the face-to-face examination of the beneficiary in the hospital issues a PMD prescription and supporting documentation that is received by the supplier within 45 days after the date of discharge.

(ii) Accessories for PMDs may be ordered by the physician or treating practitioner without conducting a face-to-face examination of the beneficiary.

(4) *Dispensing a power mobility device.* Suppliers may not dispense a PMD to a beneficiary until the PMD prescription and the supporting documentation have been received from the physician or treating practitioner who performed the face-to-face examination of the beneficiary. These documents must be received within 45 days after the date of the face-to-face examination.

(5) *Documentation.* (i) A supplier must maintain the prescription and the supporting documentation provided by the physician or treating practitioner and make them available to CMS and its agents upon request.

(ii) Upon request by CMS or its agents, a supplier must submit additional documentation to CMS or its agents to support and/or substantiate the medical necessity for the power mobility device.

(6) *Safety requirements.* The PMD must meet any safety requirements specified by CMS.

(d) Medicare Part B pays for medically necessary equipment that is used for treatment of decubitus ulcers if—

(1) The equipment is ordered in writing by the beneficiary's attending physician, or by a specialty physician on referral from the beneficiary's attending physician, and the written order is furnished to the supplier before the delivery of the equipment; and

(2) The prescribing physician has specified in the prescription that he or she will be supervising the use of the equipment in connection with the course of treatment.

(e) Medicare Part B pays for a medically necessary seat-lift if it—

(1) Is ordered in writing by the beneficiary's attending physician, or by a specialty physician on referral from the beneficiary's attending physician, and the written order is furnished to the supplier before the delivery of the seat-lift;

(2) Is for a beneficiary who has a diagnosis designated by CMS as requiring a seat-lift; and

(3) Meets safety requirements specified by CMS.

(f) Medicare Part B pays for transcutaneous electrical nerve stimulator units that are—

(1) Determined to be medically necessary; and

(2) Ordered in writing by the beneficiary's attending physician, or by a specialty physician on referral from the beneficiary's attending physician, and the written order is furnished to the supplier before the delivery of the unit to the beneficiary.

(g)(1) *Items requiring a written order.* As a condition of payment, Specified

Covered Items (as described in paragraph (g)(2) of this section) require a written order that meets the requirements in paragraphs (g)(3) and (4) of this section before delivery of the item.

(2) *Specified covered items.* (i) Specified Covered Items are items of durable medical equipment that CMS has specified in accordance with section 1834(a)(11)(B)(i) of the Act. A list of these items is updated annually in the FEDERAL REGISTER.

(ii) The list of Specified Covered Items includes the following:

(A) Any item described by a *Healthcare Common Procedure Coding System (HCPCS)* code for the following types of durable medical equipment:

(1) Transcutaneous electrical nerve stimulation (TENS) unit.

(2) Rollabout chair.

(3) Oxygen and respiratory equipment.

(4) Hospital beds and accessories.

(5) Traction-cervical.

(B) Any item of durable medical equipment that appears on the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Fee Schedule with a price ceiling at or greater than \$1,000.

(C) Any other item of durable medical equipment that CMS adds to the list of Specified Covered Items through the notice and comment rulemaking process in order to reduce the risk of fraud, waste, and abuse.

(iii) The list of specific covered items excludes the following:

(A) Any item that is no longer covered by Medicare.

(B) Any HCPCS code that is discontinued.

(3) *Face-to-face encounter requirements.*

(i) For orders issued in accordance with paragraphs (g)(1) and (2) of this section, as a condition of payment for the Specified Covered Item, all of the following must occur:

(A) The physician must document and communicate to the DME supplier that the physician or a physician assistant, a nurse practitioner, or a clinical nurse specialist has had a face-to-face encounter with the beneficiary on the date of the written order up to 6 months before the date of the written order.

(B) During the face-to-face encounter the physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist must conduct a needs assessment, evaluate, and/or treat the beneficiary for the medical condition that supports the need for each covered item of DME ordered.

(C) The face-to-face encounter must be documented in the pertinent portion of the medical record (for example, history, physical examination, diagnostic tests, summary of findings, diagnoses, treatment plans or other information as it may be appropriate). Physician must sign or cosign the pertinent portion of the medical record indicating the occurrence of a face-to-face encounter for the beneficiary for the date of the face-to-face encounter when performed by a physician assistant, a nurse practitioner, or a clinical nurse specialist. For purposes of this paragraph (g), a face-to-face encounter does not include DME items and services furnished from an “incident to” service.

(ii) For purposes of this paragraph (g), a face-to-face encounter may occur via telehealth in accordance with all of the following:

(A) Section 1834(m) of the Act.

(B)(1) Medicare telehealth regulations in § 410.78 and § 414.65 of this chapter; and

(2) Subject to the list of payable Medicare telehealth services established by the applicable PFS.

(4) *Written order issuance requirements.* Written orders issued in accordance with paragraphs (g)(1) and (2) of this section must include all of the following:

(i) Beneficiary’s name.

(ii) Item of DME ordered.

(iii) Signature of the prescribing practitioner.

(iv) Prescribing practitioner NPI.

(v) The date of the order.

(5) *Supplier’s order and documentation requirements.* (i) A supplier must maintain the written order and the supporting documentation provided by the physician, physician assistant, nurse practitioner, or clinical nurse specialist and make them available to CMS upon request for 7 years from the date of service consistent with § 424.516(f) of this chapter.

(ii) Upon request by CMS or its agents, a supplier must submit additional documentation to CMS or its agents to support and substantiate that a face-to-face encounter has occurred.

[51 FR 41339, Nov. 14, 1986, as amended at 57 FR 57688, Dec. 7, 1992; 58 FR 30668, May 26, 1993; 70 FR 50946, Aug. 26, 2005; 71 FR 17030, Apr. 5, 2006; 77 FR 69362, Nov. 16, 2012]

§ 410.39 Prostate cancer screening tests: Conditions for and limitations on coverage.

(a) *Definitions.* As used in this section, the following definitions apply:

(1) *Prostate cancer screening tests* means any of the following procedures furnished to an individual for the purpose of early detection of prostate cancer:

(i) A screening digital rectal examination.

(ii) A screening prostate-specific antigen blood test.

(iii) For years beginning after 2002, other procedures CMS finds appropriate for the purpose of early detection of prostate cancer, taking into account changes in technology and standards of medical practice, availability, effectiveness, costs, and other factors CMS considers appropriate.

(2) A *screening digital rectal examination* means a clinical examination of an individual's prostate for nodules or other abnormalities of the prostate.

(3) A *screening prostate-specific antigen blood test* means a test that measures the level of prostate-specific antigen in an individual's blood.

(4) A physician for purposes of this provision means a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act) who is fully knowledgeable about the beneficiary, and who would be responsible for explaining the results of the screening examination or test.

(5) A physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife for purposes of this provision means a physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife (as defined in sections 1861(aa) and 1861(gg) of the Act) who is fully knowledgeable about the beneficiary, and who would be responsible for explain-

ing the results of the screening examination or test.

(b) *Condition for coverage of screening digital rectal examinations.* Medicare Part B pays for a screening digital rectal examination if it is performed by the beneficiary's physician, or by the beneficiary's physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife as defined in paragraphs (a)(4) or (a)(5) of this section who is authorized to perform this service under State law.

(c) *Limitation on coverage of screening digital rectal examinations.* (1) Payment may not be made for a screening digital rectal examination performed for a man age 50 or younger.

(2) For an individual over 50 years of age, payment may be made for a screening digital rectal examination only if the man has not had such an examination paid for by Medicare during the preceding 11 months following the month in which his last Medicare-covered screening digital rectal examination was performed.

(d) *Condition for coverage of screening prostate-specific antigen blood tests.* Medicare Part B pays for a screening prostate-specific antigen blood test if it is ordered by the beneficiary's physician, or by the beneficiary's physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife as defined in paragraphs (a)(4) or (a)(5) of this section who is authorized to order this test under State law.

(e) *Limitation on coverage of screening prostate-specific antigen blood test.* (1) Payment may not be made for a screening prostate-specific antigen blood test performed for a man age 50 or younger.

(2) For an individual over 50 years of age, payment may be made for a screening prostate-specific antigen blood test only if the man has not had such an examination paid for by Medicare during the preceding 11 months following the month in which his last Medicare-covered screening prostate-specific antigen blood test was performed.

[64 FR 59440, Nov. 2, 1999, as amended at 65 FR 19331, Apr. 11, 2000]